IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: C. R. BARD, INC.,
PELVIC REPAIR SYSTEM
PRODUCTS LIABILITY LITIGATION MDL No. 2187

THIS DOCUMENT RELATES TO C. R. BARD WAVE 4 & WAVE 5 CASES BEFORE JUDGE GOODWIN:

MEMORANDUM OPINION AND ORDER
(*Daubert* Motion re: Alan Garely, M.D.)

Pending in *In re C. R. Bard, Inc.*, *2:10-md-2187*, MDL 2187, is defendant C. R. Bard, Inc. ("Bard")'s *Daubert* Motion to Exclude the Opinions and Testimony of Alan Garely, M.D. [ECF No. 4561]. The motion is now ripe for consideration because the briefing is complete. As set forth below, Bard's motion is **GRANTED.**

I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 16,000 cases currently pending, approximately 1,500 of which are in the Bard MDL, 2187 MDL.

In this MDL, the court's tasks include "resolv[ing] pretrial issues in a timely and expeditious manner" and "resolv[ing] important evidentiary disputes." Barbara J. Rothstein & Catherine R. Borden, Fed. Judicial Ctr., *Managing Multidistrict Litigation in Products Liability Cases* 3 (2011). In an effort to manage the massive

Bard MDL efficiently and effectively, the court decided to conduct pretrial discovery and motions practice on an individualized basis. To this end, I selected certain cases to become part of a "wave" of cases to be prepared for trial and, if necessary, remanded.

Upon the creation of a wave, a docket control order subjects each case in the wave to the same scheduling deadlines, rules regarding motion practice, and limitations on discovery. *See, e.g.*, Pretrial Order ("PTO") # 236 (establishing Wave 4); PTO # 244 (establishing Wave 5). To handle motions to exclude or to limit expert testimony pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), the court developed a specific procedure for cases designated in Wave 4 and Wave 5. The court instructed the parties to file briefing on general causation issues in the main MDL, MDL 2187, while specific causation *Daubert* motions, responses, and replies were to be filed in the individual member cases. To the extent that an expert is both a general and specific causation expert, the court advised the parties that they could file a general causation motion in the main MDL and a specific causation motion in an individual member case. *See* PTO # 236, at 4; PTO # 244, at 4.

II. Legal Standard

Under Federal Rule of Evidence 702, expert testimony is admissible if it will "help the trier of fact to understand the evidence or to determine a fact in issue" and (1) is "based upon sufficient facts or data" and (2) is "the product of reliable principles and methods" which (3) has been reliably applied "to the facts of the case." Fed. R.

Evid. 702. A two-part test governs the admissibility of expert testimony. The evidence is admitted if it "rests on a reliable foundation and is relevant." *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579, 597 (1993). The proponent of expert testimony does not have the burden to "prove" anything. However, he or she must "come forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998).

The district court is the gatekeeper. It is an important role: "[E]xpert witnesses have the potential to be both powerful and quite misleading"; the court must "ensure that any and all scientific testimony . . . is not only relevant, but reliable." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. at 588, 595; *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999)). I "need not determine that the proffered expert testimony is irrefutable or certainly correct" – "[a]s with all other admissible evidence, expert testimony is subject to testing by '[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.'" *United States v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006) (alteration in original) (quoting *Daubert*, 509 U.S. at 596); *see also Md. Cas. Co.*, 137 F.3d at 783 ("All *Daubert* demands is that the trial judge make a 'preliminary assessment' of whether the proffered testimony is both reliable . . . and helpful.").

Daubert mentions specific factors to guide the overall relevance and reliability determinations that apply to all expert evidence. They include (1) whether the particular scientific theory "can be (and has been) tested"; (2) whether the theory "has

been subjected to peer review and publication"; (3) the "known or potential rate of error"; (4) the "existence and maintenance of standards controlling the technique's operation"; and (5) whether the technique has achieved "general acceptance" in the relevant scientific or expert community. *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003) (quoting *Daubert*, 509 U.S. at 593-94).

Despite these factors, "[t]he inquiry to be undertaken by the district court is 'a flexible one' focusing on the 'principles and methodology' employed by the expert, not on the conclusions reached." *Westberry*, 178 F.3d at 261 (quoting *Daubert*, 509 U.S. at 594-95); *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999) ("We agree with the Solicitor General that '[t]he factors identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony.'" (citation omitted)); *see also Crisp*, 324 F.3d at 266 (noting "that testing of reliability should be flexible and that *Daubert*'s five factors neither necessarily nor exclusively apply to every expert").

With respect to relevancy, *Daubert* also explains:

> Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful. The consideration has been aptly described by Judge Becker as one of "fit." "Fit" is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes. . . . Rule 702's "helpfulness" standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.

Daubert, 509 U.S. at 591-92 (citations and internal quotation marks omitted).

III. Analysis

Dr. Alan Garely is board-certified in obstetrics, gynecology, female pelvic medicine and reconstructive surgery. *See* Pls.' Resp. in Opp'n to Def.'s Mot. to Exclude Certain Ops. of Alan Garely, M.D., at 1 [ECF No. 4599]. He offers several different opinions, a number of which Bard contends are improper: (1) narrative descriptions of Bard documents that purport to address Bard's knowledge, state of mind, or corporate conduct; (2) legal opinions; and (3) opinions about the adequacy of the warnings contained in the Instructions for Use ("IFU").

A. Narrative Descriptions of Internal Documents Addressing Bard's Knowledge, State Of Mind, or Corporate Conduct

A portion of Dr. Garely's expert report discusses Bard's knowledge and state of mind. Dr. Garely opines, for example, that:

> Bard recognized, based in part on published literature that pre-dated the launch of the Align TO, that "design of a more light weight, open pore mesh is needed" because mesh products sold for pelvic repair were, according to Bard's own internal memoranda, overengineered with regard to strength for the biologic requirement and that the design was associated with reoccurrence, adverse events, and various complications. . . .
>
> Bard's internal documents reflect that it was aware that the contraction/shrinkage rate associated with mesh products was between 30% and 50%, and that this shrinkage was directly correlated to scar plate formation, and Bard's documents acknowledge that "the postoperative scarification process significantly shrinks the tissue around the mesh, increasing the tension on the graft."

Defs.' Motion to Exclude the Ops. & Test. of Alan Garely, M.D., Ex. 1 ("Dr. Garely's Expert Report") at 14-15 [ECF No. 4561-2].

While an expert may testify as to a review of internal corporate documents solely for the purpose of explaining the basis for his or her opinions—assuming the opinions are otherwise admissible—Bard's knowledge, state of mind, or other matters related to corporate conduct are not appropriate subjects of expert testimony because opinions on these matters will not assist the jury. *See, e.g.*, *In re Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 192 (S.D.N.Y. 2009) (precluding testimony as to "the knowledge, motivations, intent, state of mind, or purposes of" a company and its employees because it "is not a proper subject for expert or even lay testimony"). Accordingly, Bard's motion is **GRANTED** insofar as Dr. Garely's opinions relate to Bard's knowledge, state of mind, and corporate conduct.

B. Legal Opinions

In the Fourth Circuit, "opinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible." *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006). Bard seeks to exclude certain opinions expressed by Dr. Garely that it believes amount to legal conclusions. For instance, Bard argues that Dr. Garely should be prevented from testifying that "omission of instructions or warnings . . . rendered the Align TO device not reasonably safe" and that the design of the Align TO was "unreasonably dangerous and defective" because they state a legal standard or draw a legal conclusion. *See* Def. Mem. of Law in Supp. of Mot. to Exclude Certain Ops. of Alan Garely, M.D., at 7 (citing Dr. Garely's Expert Report, at 6, 13). The plaintiffs, in response, do not believe that these statements draw legal conclusions from the facts. I disagree.

Here, Dr. Garely's opinion goes a step beyond the adequacy of the warnings or the efficacy of the product's design. In doing so, these opinions invade the province of the jury by stating a legal conclusion and will not be accepted at trial. *See United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006) ("[O]pinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible."); *see also Perez v. Townsend Eng'g Co.*, 562 F. Supp. 2d 647, 652 (M.D. Pa. 2008) (precluding an expert witness "from using legal terms of art" and "giv[ing] legal conclusions, such as, but not limited to, the conclusions that the [product] was 'defective,' 'unreasonably dangerous,' or was the 'proximate cause' of [the plaintiff's] injury"). Therefore, Bard's motion on this point is **GRANTED**.

C. Adequacy of the Warnings Contained in the IFU

Previously, in September 2016, I held that Dr. Garely is not qualified to opine on the adequacy of a product warning IFU merely because it included risks he has observed in his own practice without additional expertise in the specific area of product warnings. *See In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4582209, at *3 (S.D. W. Va. Sept. 1, 2016) ("Dr. Garely does not possess the additional expertise to offer expert testimony about what an IFU should or should not include.").

According to Bard, Dr. Garely remains unqualified to offer expert testimony on the adequacy of the Align product's IFU because he has no specialized knowledge of IFUs beyond his experience as a physician.

In response, in order to justify deviation from this court's prior reasoning, the plaintiffs cite Dr. Garely's deposition testimony wherein he details his involvement in the development of the IFU for the TVT sling device. *See* Pls.' Resp. in Opp'n to Def.'s Mot. to Exclude Certain Ops. of Alan Garely, M.D., at 14 [ECF No. 4599] (citing Ex. 2 ("Dr. Garely Dep.") 42:6–45:11 [ECF No. 4561-3]). Specifically, Dr. Garely stated:

> Q: You state in this report that you advised Ethicon in formulating their instructions for use; is that correct?
>
> A: This is correct.
>
> Q: What portions of the IFU did you contribute to?
>
> A: There was a group of probably 10 or 12 of us that originally went over to Sweden to learn the TVT procedure . . . and when we came back there was a core group of people . . . [that] had multiple, multiple meetings with [Ethicon] . . . where we would go over what we thought should be taught, what we thought should be discussed . . . , and what type of information should be, in *general*, placed into the IFU. It wasn't that I specifically was tasked with looking at one part of the IFU, but it was a general consensus of things that we felt should be included in the IFU.
>
> . . . .
>
> Q: Have you ever written anything that went into an instruction for use?
>
> A: Again, I don't recall whether anything that I specifically wrote was incorporated or whether it was my *concepts* as part of a team that were incorporated.
>
> . . . .
>
> Q: Do you recall what it is that you suggested that was incorporated?
>
> A: No, just the general things that I thought were important and to the device of what was known at the time.

Id. (emphasis added).

While this testimony further elucidates Dr. Garely's qualifications to testify about the risks of implanting a product and whether those risks were adequately expressed on the product's IFU, *see In re Yasmin & Yaz (Drospirenone) Prods. Liab. Litig.*, 2011 WL 6301625, at *11 (S.D. Ill. Dec. 16, 2011) ("[D]octors are fully qualified to opine on the medical facts and science regarding the risks and benefits of drugs and to compare that knowledge with what was provided in the text of labeling and warnings . . . ." (internal quotations and brackets omitted)), Dr. Garely remains unqualified to opine on whether an IFU complies with regulatory standards because his "additional expertise" – identified above – in the area of product warning derives from his general experience as a physician. *See* Dr. Garely Dep. 56:7–8 ("I'm not an expert on industry regulations."). Accordingly, Bard's motion on this point is **GRANTED.**

IV. Conclusion

To summarize, I **GRANT** Bard's *Daubert* Motion to Exclude the Opinions and Testimony of Alan Garely, M.D. [ECF No. 4561] consistent with my reasoning above.

The court **DIRECTS** the Clerk to file a copy of this Memorandum Opinion and Order in 2:10-md-2187, and the Bard Wave 4 and Wave 5 cases identified in the Exhibit attached hereto. The court further **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: September 4, 2018

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE

Exhibit A

CIVIL ACTION NUMBER	Case Name
2:14-cv-03439	Kitchen v. C. R. Bard, Inc. et al.
2:14-cv-18890	McManus v. C. R. Bard, Inc. et al.
2:14-cv-21874	McCray v. C. R. Bard, Inc. et al.
2:14-cv-23401	Barber v. C. R. Bard, Inc. et al.
2:14-cv-28943	Smith et al. v. C. R. Bard, Inc. et al.
2:16-cv-01855	Eiffler v. Sofradim Production SAS et al.